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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,185	02/08/2002	Shih-Jen Liu	13886-002001 / 01P0325	3503

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FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
TIDWELL, JUDY LILLE	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,185	LIU ET AL.	
	Examiner	Art Unit	
	Judy Lille Tidwell, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/25/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-27,38 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-27,38 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Liu and Lo

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/22/2005 and 1/25/2006 has been entered.

It is noted that applicant has amended claims 18, 21, 38, and 39 to more particularly point out and distinctly claim the subject matter.

Claims 1-17, 36-37, and 40-46 have been canceled without prejudice.

Claims 18-27 and 38-39 are currently pending and under consideration.

The restriction/election requirement set forth on 09/08/2004 between prostrate specific antigen and alpha-fetoprotein is withdrawn in view that claim 39 is examined in the previous office action mailed on 07/22/2005.

The text of those sections of Title 35, U.S. Code are not included in this action and can be found in a prior Office action.

Claim Objections

The claim objections of claims 18-27, 36-46 (from office action on 07/22/2005) are withdrawn in view of the amendments to the claims.

Claim 18 is newly objected to because of the following informalities: the limitation "wherein the composition is free of any human antigen that is not covalently bound" would be more clear if the limitation is amended to "wherein the composition is free of any human antigen that is not covalently bound to Hsp70". Appropriate correction is required.

Claim Rejections Withdrawn - 35 USC § 112

The rejection of claims 18, 21, 23, 24, 27, 38-39 under 35 USC § 112, 1st paragraph (from office action on 07/22/2005) as lacking written description is withdrawn in view of the amendments to the claims and the persuasive arguments presented by the applicant.

Claims 18-27 and 36-46 under 35 U.S.C. § 112, first paragraph (from office action on 07/22/2005) as failing to comply with the enablement requirement is withdrawn in view of the amendments to the claims and the persuasive arguments presented by the applicant.

Claims 18-27 and 36-46 under 35 U.S.C. § 112, second paragraph (from office action on 07/22/2005) as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims and the persuasive arguments presented by the applicant.

Claim Rejections Maintained - 35 USC § 103

Claims 18-23 and 38-39 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Srivastava of record (U.S. Patent No. 5,985,270) in view of Suzue et al. of record (Journal of Immunology, 1995, 156:873-879) for the reasons of record presented in the office actions mailed 11/3/2004 and 7/22/2005.

The instant claims are drawn to an immunogenic composition comprising (i) antigen-presenting cells, (ii) a purified protein containing amino acids 481-641 of the human Hsp70 covalently fused to a human antigen, and (iii) a pharmaceutically acceptable carrier.

Applicant argues (from response on 11/22/2005) that the human Hsp70 C-terminal fragment has a special property ("the unexpected finding that purified human Hsp70 is itself immunogenic") and the prior art of record does not point one of ordinary skill to use the C-terminal specific fragment, amino acids 481-641 of human Hsp70.

However, this argument is not commensurate in scope of the claims. The base claim 18 recites "a purified protein ... consisting essentially of ... a fragment of human

Hsp70...". See MPEP 2111.03 (R-3) "For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising". See PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. Therefore, the open language in claim 18 allows for broad interpretation such that the claim limitation includes the full length Hsp70 taught by Srivastava (U.S. Patent No. 5,985,270).

Srivastava (U.S. Patent No. 5,985,270, column 26, claims 21-23) teaches a composition comprising antigen presenting cells, a pharmaceutically acceptable carrier, and a purified complex of a heat shock protein, such as hsp70, non-covalently bound to an antigenic molecule immunospecific to cancer.

Srivastava does not teach a covalently fused heat shock protein and antigen.

Suzue et al. (page 873, abstract) teach a fusion protein with a covalent linkage of Mycobacteria Hsp70 to the antigen HIV-1 p24. One of ordinary skill in the art would have been motivated to covalently link antigens to human Hsp70, making a Hsp70 fusion protein, based on the teachings of Srivastava and Suzue et al., because they can be easily produced and purified in large amounts and can be more easily characterized because they contain identical numbers and positions of the fused antigen as taught by Suzue et al. None of these advantages are Mycobacterial Hsp70-specific. Therefore, a person of ordinary skill in the art would have a reasonable expectation of success with these advantages when using human Hsp70 and the antigen PSA as was taught by Srivastava. The rejection is maintained.

Claims 24-27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Srivastava of record (U.S. Patent No. 5,985,270) in view of Suzue et al. of record (Journal of Immunology, 1995, 156:873-879) and in further view of Tong et al. of record (Cancer Research, 2001 61:7530-7535) for the reasons of record presented in the office actions mailed 7/22/2005.

Applicant argues (from response on 11/22/2005) that Tong et al. does not teach or suggest a composition that contains a fragment of human Hsp70 nor an antigen and

therefore claims 24-27 are not rendered obvious by Srivastava, Suzue et al. and Tong et al.

As stated above, applicant's arguments based on the Hsp70 C-terminal fragment is not commensurate in scope of the claims due to the transitional phrase "consisting essentially of" is interpreted as "comprising". The teachings of Srivastava and Suzue et al. have been discussed above. These teachings differ from the claimed invention in that they do not disclose the use of cytotoxic compounds, such as chemotherapeutic agents, with a composition consisting of dendritic cells, heat shock fusion proteins, and a pharmaceutically acceptable carrier.

Tong et al. (abstract) disclose the use of systemic chemotherapy in addition to the administration of dendritic cells in mouse tumor models. The administration of dendritic cells is combined with systemic chemotherapy, and such a combination leads to the advantages of marked tumor suppression and persistent antitumor immune memory (Fig. 1, 2, page 7530, 7534). It would have been obvious to one of ordinary skill in the art at the time of the invention to include a chemotherapeutic agent with a composition comprising dendritic cells and a heat shock fusion protein based on the successful use of dendritic cell administration and chemotherapy to cause tumor regression in an animal model as taught by Tong et al. Motivation to do so comes from the teaching that chemotherapy combined with dendritic cell administration is more effective in treating tumors that dendritic cell administration alone.

Applicant's arguments have been fully considered but not found persuasive because, as explained above, the transitional phrase "consisting essentially of" is interpreted as "comprising". Therefore, the claimed invention reads on the fusion protein including the full length Hsp70 taught by Srivastava (U.S. Patent No. 5,985,270).

Conclusion

Claims 18-27 and 38-39 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy Lille Tidwell, PhD whose telephone number is 571-272-5952. The examiner can normally be reached on 8:00AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JLT
Art Unit 1642

MISOOK YU
PRIMARY EXAMINER